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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,814	01/19/2005	Andrew Lennard Lewis	Q83535	6809
23373 7590 02/22/2010 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037				
EXAMINER FUBARA, BLESSING M				
ART UNIT		PAPER NUMBER		
1618				
NOTIFICATION DATE		DELIVERY MODE		
02/22/2010		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/506,814

Applicant(s)

LEWIS ET AL.

Examiner

BLESSING M. FUBARA

Art Unit

1618

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 December 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) 27 and 36-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22, 28-35 and 45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The examiner acknowledges receipt of request for extension of time, complaint amendment and remarks filed 12/09/09. Claim 18 is amended; new claim 45 is added. Claims 1-26 and 28-45 are pending. Claims 23-26 and 36-44 are withdrawn from consideration.

Election/Restrictions

1. Applicant's election with traverse of claims 1-22 and 28-35, the zwitterionic monomer 2-methacroyloxyethyl phosphorylcholine (MPC) and ionic monomer 2-dimethylaminoethylmethacrylate used in Example 2 in the reply filed on 12/08/08 is acknowledged. The traversal is on the ground(s) that the prior art references, Storch, Bronich and Kabanov cited by the examiner do not disclose block copolymers having zwitterionic blocks. This is not found persuasive because while Storch, Bronich and Kabanov do not teach zwitterionic blocks, Stratford teaches polyion complex comprised of zwitterionic polymer and ionic monomer for delivery of pharmaceutically active agent agents and diagnostic agents.

The election requirement was deemed proper and the requirement was made FINAL.

Response to Arguments

2. Applicant's arguments filed 12/09/09 have been fully considered but they are not persuasive.
3. Applicant has further traversed the restriction requirement by arguing that Stratford does not remedy Kabanov, Storch and Bronich.
4. In response to the above, the examiner notes that Stratford, does not have to remedy the deficiencies of Kabanov, Storch and Bronich because Stratford teaches the limitations of claim 1

and because claim 1 is taught by Stratford, unity of invention is still lacking. Stratford stands by itself to anticipate claim 1.

Response to Arguments

Previous rejections that are not reiterated herein are withdrawn.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-22 and 28-35 and 45 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-43 of copending Application No. 10/542,333 in view of Storch et al. (WO 98/22517). The copending claims prepare the polyion block copolymer of the instant claims. The copending claims do not have

ionic drugs. But Storch teaches that polyion block copolymers of the type claimed are capable of trapping heparin, negatively charged molecule (see the whole document with emphasis on the abstract, page 5, page 7). Therefore, taking the teaching of Storch in combination with the copending claims, multi-ionic compounds such as nucleic acid can be effectively trapped for later release.

This is a provisional obviousness-type double patenting rejection.

7. Claims 1-22 and 28-35 and 45 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 33-78 of copending Application No. 10/501,393 in view of Storch et al. (WO 98/22517). The copending claims teach the same polyion block copolymer that is associated with pharmacological or diagnostic active compound. Storch teaches that polyion block copolymers of the type claimed are capable of trapping heparin, negatively charged molecule (see the whole document with emphasis on the abstract, page 5, page 7). Therefore, taking the teaching of Storch in combination with the copending claims, multi-ionic compounds such as nucleic acid can be effectively trapped for later delivery.

This is a provisional obviousness-type double patenting rejection.

8. Claims 1-22 and 28-35 and 45 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 29-50 of copending Application No. 10/544,113 in view of Storch et al. (WO 98/22517). The copending claims teach the same polyion block copolymer that is associated with pharmacological or diagnostic active compound. Storch teaches that polyion block copolymers of the type claimed are capable of trapping heparin, negatively charged molecule (see the whole document with emphasis on the

abstract, page 5, page 7). Therefore, taking the teaching of Storch in combination with the co-pending claims, multi-ionic compounds such as nucleic acid can be effectively trapped for later delivery.

This is a provisional obviousness-type double patenting rejection.

Response to Arguments

9. Applicant's arguments filed 12/09/09 have been fully considered but they are not persuasive.

10. Applicant argues that Storch does not disclose polyion block copolymers and as such the combination is incorrect.

11. The examiner disagrees. Storch teaches the use of polymers, copolymers and terpolymers. Polymers are random, alternating or block or graft. But terpolymer of the nature YBQ (see at least page 8, line 10; page 10, lines 30, 37) is a copolymer and terpolymers have structure of block copolymers of the nature (ABC)(ABC)(ABC)---, so that a generic block copolymer reads of terpolymer. Also, the copending claims are directed to block copolymers. The difference is that the block copolymers of the copending claims are not associated with biologically active agent/compound. The terpolymer of Storch structurally having a terpolymer of the block structure ABC, have monomers that are the same polyionic and have associated biologically active agent/compound. Therefore, the teaching of Storch provides a suggestion that the block copolymers of the co-pending claims would be effective carriers for biologically active compounds. The rejection is maintained.

12. **Declaration by Andrew Lennard Lewis**

13. The declaration under 37 CFR 1.132 filed 12/09/09 is insufficient to overcome the rejection of claims 1-22 and 28-35 and 45 based upon copending claims of 10/542333, 10/501393, and 10/544,113, all in view of Storch as set forth in the last Office action because: terpolymers acknowledged by the declaration as being disclosed by Storch is a copolymer, which also has the structure of block copolymer. The terpolymer of structure 5, Fig. 1 in the declaration is the structure of the terpolymer of Storch. While the declaration admits that Storch did not mention the process used to form the copolymer, the declaration concludes that the copolymers formed by the examples must be random without showing why and how the polymers are random. Fig. 1-4 do not appear in the Storch reference and is thus reasonable to assume that the declaration is referring to Figure 1 : Copolymer Types submitted with the declaration. These are diagrams depicting types of copolymers and do not represent the Storch reference. While the declaration argues against the terpolymer of Storch being a block, it is noted that, Storch does not name the copolymers as random except for the teaching that these are terpolymers of the type YBQ. Further, the declaration admits that Storch does not mention the process used in the polymerization specific type and concludes that the terpolymer of Storch is random and not block or alternating. Concluding arguments that the terpolymers of Storch does not take the place of showing that the terpolymer of Storch is random and not block.

14. Also, the copending claims teach block copolymer having zwitterionic groups of the claims and Storch teaches copolymers having the same zwitterionic groups that are associated with biologically active compound, there is thus the motivation to use the block copolymers of the copending claims as carrier for biologically active compound.

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

16. Claims 1, 20, 21, 33 and 34 and new claim 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Stratford et al. (WO 00/28920) for reasons of record.

17. Stratford teaches the polymer of the type claimed (see the whole document with emphasis on the abstract and pages 6-13). These polymers have associated with imaging agents (page 3, lines 5-13). The biologically active compound of claim 1 broadly reads on the bio-imaging compounds. Claims 20, 21, 33 and 34 are product by process claims and these claims are thus met by Stratford.

Response to Arguments

18. Applicant's arguments filed 12/09/09 have been fully considered but they are not persuasive.

19. Applicant argues that paragraphs 6 and 7 of the declaration by Mr. Lewis shows that the copolymer of Stratford are random copolymers prepared by radical polymerization.

20. The examiner disagrees that the free radical polymerization produces only random copolymers. A factual showing is necessary to show that the polymer of Stratford is random and not block. It is known in the art that free radical polymerization produces block copolymers as evidenced by: abstract; column 1, lines 29-32; column 2, lines 20-22; column 3, lines 30-32; column 6, lines 7-9; column 7, lines 11-13, 38-41; column 15, lines 50-52 and claim 4 of US

6,310,175 and column 1, lines 5-7, 18-20 and 26-31 of US 6,291,620. The declaration is addressed below.

21. Declaration by Andrew Lennard Lewis

22. The declaration under 37 CFR 1.132 filed 12/09/09 is insufficient to overcome the rejection of claims 1, 20, 21, 33 and 34 based upon Stratford as set forth in the last Office action because: Radical polymerization is known in the art to produce block copolymers (see abstract; column 1, lines 29-32; column 2, lines 20-22; column 3, lines 30-32; column 6, lines 7-9; column 7, lines 11-13, 38-41; column 15, lines 50-52 and claim 4 of US 6,310,175 and column 1, lines 5-7, 18-20 and 26-31 of US 6,291,620). Therefore, the arguments in paragraphs 6 and 7 of the declaration are insufficient to overcome the rejections. A factual showing that the polymers of Stratford are not block copolymers have not been presented.

Claim Rejections - 35 USC § 103

23. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

24. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

25. Claims 1-22 and 28-35 and new claim 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stratford et al. (WO 00/29481) in view of Storch et al. (WO 98/22517) for reasons of record.

26. Stratford discloses polyion complex of the type claimed (see the whole document with emphasis on the abstract, structures on page 9, 10 and 11 corresponding to X, formula VII corresponds to claims 8, 43; see pages 16-27). Proteins such as fibrinogen are adsorbed onto the polymer (page 16). Stratford does not teach the presence of ionic compound in the polymer. But Storch teaches that polyion block copolymers of the type claimed are capable of trapping heparin, negatively charged molecule (see the whole document with emphasis on the abstract, page 5, page 7). Therefore, taking the teaching of Storch in combination with Stratford multi-ionic compounds such as nucleic acid can be effectively trapped for later delivery.

Response to Arguments

27. Applicant's arguments filed 12/09/09 have been fully considered but they are not persuasive.

28. Applicant argues that Storch teaches only random copolymers and does not teach block copolymer according to the declaration by Mar. Lewis at paragraph 5 of the declaration.

29. Response: The examiner disagrees because Storch is silent as to random, block or alternating copolymer. Storch teaches terpolymer copolymer having the structure YBQ, which has the same structure as a block. The argument that Storch does not teach a block copolymer

does not take the place of factually showing that the terpolymer of Storch having the structure YBQ is random copolymer. Storch is relied upon for teaching ionic compound in association with copolymer having the same units of monomers as the copolymer of Stratford. The declaration by Lewis is addressed below.

30. Declaration by Andrew Lennard Lewis

31. The declaration under 37 CFR 1.132 filed 12/09/09 is insufficient to overcome the rejection of claims 1-22, 28-35 and 45 based upon Stratford in view of Storch as set forth in the last Office action because: the declaration that the YBQ terpolymer of Storch is not a block polymer is not persuasive because the claimed block copolymer reads of the terpolymer YBQ of Storch, which has a block structure and the declaration has not factually shown that the terpolymer of Storch is random and not block. Fig. 1-4 is submitted with the declaration to show the types of copolymers and do not represent Storch.

32. Furthermore, Storch is relied upon for teaching that ionic compound is associated with copolymers comprised of units present in the copolymer of Stratford WO 0029481.

33. Claims 1-22 and 28-35 and new claim 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stratford et al. (WO 00/29481) and Koulik et al. (US 6,270,788) for reasons of record.

34. Stratford discloses polyion complex of the type claimed (see the whole document with emphasis on the abstract, structures on page 9, 10 and 11 corresponding to X, formula VII corresponds to claims 8, 43; see pages 16-27). Proteins such as fibrinogen are adsorbed onto the polymer (page 16). Stratford does not teach the presence of ionic compound in the polymer.

Koulik teaches a terpolymer of MPC, alkyl acrylate and aminoethyl acrylate (column 6, lines 4-40) and biomolecules such as heparin (column 7, lines 15-22) and hormones, growth factors, nucleic acids, dyes, DNA and RNA that can be attached. Claims 21, 22, 33 and 34 are product by process claims. The terpolymer of Koulik and the copolymer of Stratford meet the polymer limitations of claims 1, 8-22, 28-34 and 45. The biomolecules meet the requirement of claims 2-6. Therefore, taking the teachings of Stratford and Koulik, one having ordinary skill in the art at the time the invention was made would attach biomolecules to the MPC-acrylate block copolymers for anticipated delivery of these biomolecules.

Response to Arguments

35. Applicant's arguments filed 12/09/09 have been fully considered but they are not persuasive.

36. Applicant argues that Koulik does not remedy the deficiencies of Stratford 481 because the statement in the last office action that the terpolymer in Koulik meets the limitation of the claims is incorrect and also that column 6, lines 4-40 refer to blocks in Figure 1b showing schematic representation of a copolymer formed from three monomers. Applicant further argues that the declaration by Mr. Lewis states that the passage cited by the examiner does not support block copolymer. Applicant also argues that Koulik does not disclose reactive tertiary amine pendant group that bind to heparin as required by claim 45.

37. Response: The declaration by Mar Lewis will be addressed separately. Koulik describes hydrophilic block (column 6, line 4), hydrophobic block (column 6, line 20) and function group (column 6, line 30) and also Fig.1B is a depiction of block copolymer that is used as a coating in Koulik and the blocks in Fig. 1B and 1C represents terpolymer structure and a block structure

and the fact that Koulik specifically teaches the presence of block indicates block copolymer. With regards to applicant's argument that Koulik does not disclose reactive amine group that would bond to heparin, it is noted that claim 45 does not have describe tertiary amine groups. Claim 45 is a combination of claims 1, 8, 13.

38. Declaration by Andrew Lennard Lewis

39. The declaration under 37 CFR 1.132 filed 12/09/09 is insufficient to overcome the rejection of claims 1-22, 28-35 and 45 based upon Stratford and Koulik as set forth in the last Office action because: While the declaration is correct that Koulik does not mention terpolymer, it is true that Koulik teaches block copolymers (See Figs. 1B and 1C, (see column 6, lines 4, 20 and 30). The declaration says that the Fig. 1 is the patent specification and not the polymer itself, but column 2, lines 58-64 specifically states that FIG. 1B "depicts a block representation of suitable polymer coating used in the present invention" and "FIG. 1C illustrates the structure of a copolymer coating" and it is thus confusing as to why the declaration should assert that the block copolymer referred to in the specification of Koulik is not the polymer of Koulik. The reference of the declaration to method described by Koulik in the formation of the copolymer does not overcome Koulik because the claims are directed to products and not to process/method of making the product. Claims 1 and 45, the generic claims do not recite molar ratios.

40. The declaration does not provide data or factual showing that the copolymer or the block polymers referred to by Koulik are in fact random and not blocks.

41. Therefore, the arguments in the declaration is insufficient to overcome the rejections. A factual showing that the polymers of Koulik are not block copolymers have not been presented.

42. No claim is allowed.

43. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

44. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on Monday to Thursday from 7 a.m. to 5:30 p.m.

45. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

46. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR

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system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Blessing M. Fubara/

Primary Examiner, Art Unit 1618